

510(k) SUMMARY: COALITION™ SPACER

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

Device Name: COALITION™ Spacer

Classification: Product Code ODP. Class II.
21 CFR §888.3080 Intervertebral body fusion device.

Predicate(s): PATRIOT™ Cervical Spacer (Colonial™ ACDF Spacer)
K072991 and other legally marketed devices.

Device Description:

The COALITION™ Spacer is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacer is to be filled with autogenous bone graft material.

The COALITION™ Spacer is made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The anterior portion of the implant and the mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

Intended Use:

The COALITION™ Spacer is a stand-alone interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION™ Spacer is to be filled with autogenous bone graft material, and is to be used with two titanium alloy screws which accompany the implant.

Basis for Substantial Equivalence:

The COALITION™ Spacer has been evaluated in accordance with the "Class II Special Controls Guidance Document: Intervertebral Fusion Device", June 12, 2007 and have been found to meet the criteria set forth in the guidance document in terms of indications, design, and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Globus Medical, Inc.
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Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

SEP 12 2011

Re: K083389
Trade/Device Name: COALITION™ Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: March 23, 2009
Received: March 24, 2009

Dear Dr. Baker:

This letter corrects our substantially equivalent letter of March 26, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K083389

Device Name: COALITION™ Spacer

Indications:

The COALITION™ Spacer is a stand-alone interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION™ Spacer is to be filled with autogenous bone graft material, and is to be used with two titanium alloy screws which accompany the implant.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

16683389
510(k) Number